MAR 2 0 2000

K000103

MEDICAL INSTRUMENT

510(k) Summary

(a) (1) Submitter's name, address

AVL Scientific Corporation
235 Hembree Park Drive
Roswell, GA 30076

Contact Person

Randy Byrd
Director, Quality Assurance
770.576.5000 x 631

Date of preparation of this summary: 12 January 2000

(2) Device trade or proprietary name: AVL OPTI R Analyzer

Device common or usual name or classification name

pH, Blood Gas, Electrolyte, hemoglobin and oxygen saturation analyzer

PRODUCT NOMENCLATURE	REGULATION	CLASSIFICATION NUMBER	CLASS	PANEL
ELECTRODE, ION-SPECIFIC, POTASSIUM	862.1600	75 CEM	II	CHEMISTRY
ELECTRODE, ION-SPECIFIC, CALCIUM	862.1145	75 JFP	II	CHEMISTRY
ELECTRODE, ION-SPECIFIC, SODIUM	862.1665	75 JGS	II	CHEMISTRY
ELECTRODE, BLOOD GASES (PCO_2, PO_2) AND pH	862.1120	75 CHL	II	CHEMISTRY
SYSTEM, HEMOGLOBIN, AUTOMATED	864.5620	81 GKR	II	HEMATOLOGY
OXIMETER, WHOLE BLOOD	864.7500	81 GLY	II	HEMATOLOGY

(3) Substantial Equivalence

The AVL OPTI is substantially equivalent in function, safety and efficacy to a number of currently marketed devices known as 'Combi Analyzers' and 'Point of Care' analyzers, Specifically: Chiron 865 [K946206], AVL OMNI [K990092], Diametrics IRMA [981270], I-STAT 200 [940918], as well as electrolyte analyzers such as AVL 9181 [972763] and IL 943 Flame Photometer [K823480]. The OPTI R is modified design of the AVL OPTI Critical Care Analyzer [K974784, 984299] to allow multiple sample analyses within a single sensor cassette.

(4) Description of the new device

The AVL OPTI R is a small [4.9 x 14.3 x 9.8 in, 10 lbs], instrument using optical fluorescence for the measurement of pH, PCO_2, PO_2, sodium, potassium and ionized calcium of whole blood, plasma or serum as appropriate. In addition, it uses optical reflectance for the measurement of total hemoglobin and oxygen saturation. A disposable, multiple-use cassette containing six optical fluorescence sensors is packaged in a sealed foil pouch which bears a bar-coded label with calibration and identification information. The OPTI can perform up to 7 tests on a single sample and provide analysis of up to fifty blood samples and 35 quality control samples on a single cassette.

AVL SCIENTIFIC CORPORATION
235 Hembree Park Dr. Roswell, GA USA 30076 Tel. (770) 576-5000 Sales (800) 421-4646 Service (800) 526-2272 Fax (770) 576-5010

(5) Intended use of the device

The AVL OPTI R Analyzer is intended to be used for the measurement of pH, PCO_2, PO_2, sodium, potassium, ionized calcium, total hemoglobin content and oxygen saturation in samples of whole blood, serum or plasma in either a traditional blood gas, clinical laboratory setting or point-of-care locations by personnel minimally qualified to perform and report these results.

(6) Technological characteristics of the device.

Principles of Measurement

The OPTI R Analyzer uses fluorescence optode technology similar to that used in commercially available products since late 1983 and is unchanged in principle of operation from the originally submitted 510(k) for the OPTI Critical Care Analyzer. The measurement of total Hemoglobin (ctHb) and oxygen saturation (SO_2) is accomplished by optical scattering.

Calibration

A disposable, multiple-use cassette contains all sensors, a SnapPak™ is provided which contains calibration buffer and waste resceptacle, and an on-board gas cannister contains a precise mixture of CO2 and O2 in nitrogen needed for calibration of gas sensors and pH. Calibration verification is performed automatically with each sample immediately prior to use. No other calibration is required for the usual operation of this device for the measurement of pH, PCO_2, PO_2, Na^+, K^+, or iCa^{++}. Total hemoglobin and SO_2 are calibrated at 6-month intervals.

(b) (1) Summary of non-clinical tests submitted with the premarket notification for the device.

The AVL OPTI R Analyzer has been tested and found to comply with EN 50081-1, FCC Class B, EN 50081-2 and IEC 1010-1.

Precision

Typical Within-Run (Swr), Between-Day (Sdd) and Total (ST) precision were determined from one or two runs per day over 20 days on two AVL OPTI instruments in simulated low- and high-use tests using samples: serum, reduced bovine hemoglobin solution, whole blood and three levels of aqueous quality control solution.

Linearity

Wherever possible, linearity for the OPTI measurement has been established against reference materials or methods. Linearity for pH of whole blood is established by measurement of blood specimens which were tonometered to various CO_2 values, and measured on an AVL 995 pH/Blood Gas Analyzer standardized to N.I.S.T. traceable pH buffers, and on OPTI R Analyzers.

Interferences[1]

Representative samples taken the published guidelines for evaluation of interference substances and identified from literature were evaluated.

(b) (2) Summary of clinical tests submitted with the premarket notification for the device.

Clinical testing was conducted to demonstrate the correlation of AVL OPTI R Analyzer to predicate devices in a clinical setting, operated by personnel trained to perform and report these analyses. Specimens analyzed in these tests were remnant from patient specimens of both whole blood and plasma collected for routine analysis on existing instrumentation.

In all evaluations, there was no significant difference in mean values ($P<0.05$) obtained on measurement by the AVL OPTI R from those of the predicate devices.

(b) (3) Conclusions drawn from the clinical and non-clinical trials.

Analysis of the comparative measurement presented in the 510(k) for this device, together with the linearity and precision data collected during these clinical and non-clinical trials demonstrates that the AVL OPTI R is safe, effective, and equivalent to those predicate devices to which it is compared.

[1] NCCLS. Interference Testing in Clinical Chemistry; Proposed Guideline. NCCLS Document EP7-P. NCCLS, 771 East Lancaster Avenue, Villanova, Pennsylvania 19085, 1986.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 20 2000

Mr. Randy Byrd
Director, Quality Assurance
AVL Scientific Corporation
235 Hembree Park Drive
Roswell, Georgia 30076

Re: K000103
Trade Name: AVL OPTI R Analyzer
Regulatory Class: II
Product Code: CHL
Dated: January 12, 2000
Received: January 13, 2000

Dear Mr. Byrd:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: K000103

Device Name: AVL OPTI R Analyzer

The AVL OPTI R Analyzer intended to be used for the measurement of pH, PCO_2, PO_2, Na^+, K^+, iCa^{++}, *c*tHb and oxygen saturation in whole blood, serum and plasma as appropriate by minimally trained personnel qualified to perform and to report these values in either a traditional blood gas, clinical laboratory setting or point-of-care locations by personnel minimally qualified to perform and report these results.

For Professional Use Only
For *In Vitro* Diagnostic Use

Indications for Use[1,2]

pH

The pH value of the blood may be the single most valuable factor in the evaluation of the acid-base status of a patient. The pH value is an indicator of the balance between the buffer (blood), renal (kidney) and respiratory (lung) systems, and one of the most tightly controlled parameters in the body. The causes of abnormal blood pH values are generally classified as:

- primary bicarbonate deficit — metabolic acidosis
- primary bicarbonate excess — metabolic alkalosis
- primary hypoventilation — respiratory acidosis
- primary hyperventilation — respiratory alkalosis

An increase in blood, serum or plasma pH (*alkalemia*) may be due to increased plasma bicarbonate, or a feature of respiratory alkalosis due to an increased elimination of CO_2 due to hyperventilation.

A decrease of pH value (*acidemia*) in blood, serum or plasma may occur due to an increased formation of organic acids, an increased excretion of H^+-ions in certain renal disorders, an increased acid intake such as in salicylate poisoning or loss of alkaline body fluids. Respiratory acidosis is the result of a decreased alveolar ventilation and may be acute, as the result of pulmonary edema, airway obstruction or medication, or maybe be chronic, as the result of obstructive or restrictive respiratory diseases.

The composition of serous body fluids: pleural, pericardial, ascitic and cerebrospinal fluid, is similar to serum and plasma in electrolyte content and pH. The AVL OPTI may be used for the analysis of these fluids, limited to a pH in the

[1] Tietz, Norbert W., Ed., Clinical Guide to Laboratory Tests, 2nd Ed., (Philadelphia: W.B.Saunders, Co., 1990) p.436.
[2] Burtis C, Ashwood E (Eds.), Tietz Textbook of Clinical Chemistry, 2nd Ed., (Philadelphia: W.B.Saunders, Co., 1994) pp.1354-1360,2180-2206.

range between 6.8 and 7.7, as long as care is taken to ensure the specimen to be analyzed is clear of fibrin clots or other debris which may block the sample transport in the cassette.

Pleural fluid[3]

The pH measurement of pleural fluid can be a clinically useful tool in the management of patients with parapneumonic effusions. Patients with pneumonia may develop effusions when the infectious process extends to the visceral pleura, causing exudation of fluid into the pleural space. Fluids are divided into potentially benign and complicated effusions on the basis of pH. Fluids with a pH greater than 7.30 resolve spontaneously, whereas a pH less than 7.20 is an indication of tube drainage.

PCO_2

The PCO_2 value of arterial blood is used to assess how well the body eliminates carbon dioxide in relation to the metabolic rate of CO_2 production.

An arterial PCO_2 below the normal range is termed respiratory alkalosis and indicates *hypocapnia*, a condition caused by increased alveolar ventilation such as hyperventilation. An arterial PCO_2 above the normal range is termed respiratory acidosis and indicates *hypercapnia*, a sign of hypoventilation and failure, resulting from cardiac arrest, chronic obstructive lung disease, drug overdose, or chronic metabolic acid-base disturbances.

PCO_2

The PO_2 value of arterial blood has become the primary tool for the evaluation of arterial oxygenation status. Values below the normal arterial PO_2 (arterial *hypoxemia*) are usually caused by pulmonary, circulatory, or respiratory abnormalities (e.g. bronchial obstruction, vascular problems, decrease in cardiac output, increased oxygen demand, anatomical heart defect, low inspired O_2 content). Generally, PO_2 levels above 100 mmHg do not contribute significantly to the oxygen content since, with normal hemoglobin concentrations, 80 - 100 mmHg, PO_2 provides a 97 % saturation level, and a level greater than 100 % cannot be achieved.

Sodium

Sodium is the major cation of extracellular fluid. Its primary functions in the body are to chemically maintain osmotic pressure and acid-base balance and to transmit nerve impulses. Sodium functions at the cell membrane level by creating an electrical potential between different cell membranes causing the transmission of nerve impulses and neuromuscular excitability to be maintained. Sodium is involved in some enzyme catalyzed reactions as a cofactor. The body has a strong tendency to maintain a total base

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[3] Kaplan LA, Pesce AJ. Clinical Chemistry: Theory, analysis and correlation, 2nd Ed. (St.Louis: C.V.Mosby Co. 1989) p 590-591.

content, and only slight changes are found even under pathologic conditions.

Low sodium values, *hyponatremia*, usually reflect a relative excess of body water rather than a low total body sodium. Reduced sodium levels may be associated with: low sodium intake; sodium losses due to vomiting or diarrhea with adequate water and inadequate salt replacement, diuretics abuse, or salt-losing nephropathy; osmotic diuresis, metabolic acidosis; adreocortical insufficiency; congenital adrenal hyperplasia; dilution type due to edema, cardiac failure, hepatic failure; and hypothyroidism.

Elevated sodium values, *hypernatremia*, are associated with conditions with water loss in excess of salt loss through profuse sweating, prolonged hyperpnea, severe vomiting or diarrhea, diabetes insipidus or diabetic acidosis; increased renal sodium conservation in hyperaldosteronism, Cushing's syndrome; inadequate water intake because of coma or hypothalamic diseases; dehydration; or excessive saline therapy.

The sodium value obtained may be used in the diagnosis or monitoring of all disturbances of the water balance, infusion therapies, vomiting, diarrhea, burns, heart and kidney insufficiencies, central or renal diabetes insipidus, endocrine disturbances and primary or secondary cortex insufficiency of the adrenal gland or other diseases involving electrolyte imbalance.

Potassium

Potassium is the major cation in the intracellular fluid and functions as the primary buffer within the cell itself. Ninety percent of potassium is concentrated within the cell, and damaged cells release potassium into the blood. Potassium plays an important role in nerve conduction, muscle function, and helps maintain acid-base balance and osmotic pressure.

Elevated potassium levels, *hyperkalemia*, can be found in oligouria, anemia, urinary obstruction, renal failure due to nephritis or shock, metabolic or respiratory acidosis, renal tubular acidosis with the K^+/H^+ exchange and hemolysis of the blood. Low potassium levels, *hypokalemia*, can be found in excessive loss of potassium through diarrhea or vomiting, inadequate intake of potassium, malabsorption, severe burns and increased secretion of aldosterone. High or low potassium levels may cause changes in muscle irritability, respiration and myocardial function.

The potassium value obtained may be used to monitor electrolyte imbalance in the diagnosis and treatment of infusion therapies, shock, heart or circulatory insufficiency, acid-base imbalance, therapy with diuretics, all kinds of kidney problems, diarrhea and hyper- and hypo-function of adrenal cortex and other diseases involving electrolyte imbalance.

Ionized Calcium

Calcium in blood is distributed as free calcium ions (50%) bound to protein, mostly albumin (40%) and 10% bound to anions such as bicarbonate, citrate, phosphate

and lactate. However, only ionized calcium can be used by the body in such vital processes as muscular contraction, cardiac function, transmission of nerve impulses and blood clotting. The OPTI CCA measures the ionized portion of the total calcium. In certain disorders such as pancreatitis and hyperparathyroidism, ionized calcium is a better indicator for diagnosis than total calcium.

Elevated calcium, *hypercalcemia*, may be present in various types of malignancy, and calcium measurements may serve as biochemical markers. In general, while ionized calcium may be slightly more sensitive, either ionized or total calcium measurements have about equal utility in the detection of occult malignancy. Hypercalcemia occurs commonly in critically ill patients with abnormalities in acid-base regulation and losses of protein and albumin, which gives a clear advantage to monitoring calcium status by ionized calcium measurements.

Patients with renal disese caused by glomular failure often have altered concentrations of calcium, phosphate, albumin, magnesium and pH. Since these conditions tend to change ionized calcium independently of total calcium, ionized calcium is the preferred method of accurately monitoring calcium status in renal disease[19].

Ionized calcium is important for diagn0osis or monitoring of: hypertension management, parathyroidism, renal diseases, malnutrition, kidney stoes, multiple myeloma and diabetes mellitus.

total Hemoglobin concentration (ctHb)

The hemoglobin is the main component of erythrocytes. It serves as the vehicle for transportation of oxygen within the bloodstream and each gram/dL of hemoglobin can carry 1.39 mL of oxygen. The oxygen combining capacity of the blood is directly proportional to the hemoglobin concentration rather than to the number of red blood cells (RBC), because some red cells contain more hemoglobin than the others.

Although oxygen transport is the main function of hemoglobin, it also serves as an important buffer in the extracellular fluid. Decreases in the amount of hemoglobin can come about as a result of a decreased concentration of hemoglobin in the erythrocytes, or a decreased number of erythrocytes that contain a normal concentration of hemoglobin.

Decreased levels are found in anemia states, hyperthyroidism, severe hemorrhage and hemolytic reactions due to transfusions of incompatible blood, reaction to chemical, infectious and physical agents as well as various systemic diseases. Increased levels are found in hemoconcentration of the blood, chronic obstructive pulmonary disease and congestive heart failure.

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[19] Burritt MF, Pierides AM, Offord KP: Comparative studies of total and ionized serum calcium values in normal subjects and in patients with renal disorders. Mayo Clinic Proc. 55:606, 1980.

ctHb gives valuable information in an emergency situation if interpreted not in an isolated fashion but in conjunction with other pertinent laboratory data.

ctHb is used to screen for disease associated with anemia, to determine the severity of anemia, to follow the response to treatment for anemia and to evaluate polycythemia.

Oxygen Saturation (SO_2%)

When each heme group of the hemoglobin molecule is associated with one molecule of oxygen, the hemoglobin is referred to as oxyhemoglobin (O_2Hb). The amount of oxyhemoglobin, expressed as a fraction of the total available hemoglobin is termed, hemoglobin oxygen saturation (SO_2). The largest portion (about 98%) of blood oxygen content is the oxygen bound to hemoglobin. The reference interval for arterial blood from healthy adults is typically 94 to 98%[4]. Decrease in SO_2 below the critical level necessary for tissue oxygen saturation is a grave clinical situation. Low oxygen saturation may be caused by many of the same factors responsible for arterial *hypoxemia*, as well as from unusually large amounts of non-functional hemoglobins, high concentrations of deoxyhemoglobin, chemically altered hemoglobin or factors affecting the affinity of hemoglobin for oxygen, including: temperature, pH, PCO2, 2,3-DPG concentration and type of hemoglobin.[5]

[4] Siggaard-Andersen O, Durst RA, Maas AHJ. IFCC/IUPAC approved recommendation (1984) on physicochemical quantities and units in clinical chemistry. *J Clin Chem Clin Biochem*. 25:369-391, 1987.

[5] Burtis C, Ashwood E (Eds.), Tietz Textbook of Clinical Chemistry, 2nd Ed., (Philadelphia: W.B.Saunders, Co., 1994) pp.1354-1360,2180-2206.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K000103

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

510(k) Number _____

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Division of Clinical Laboratory Devices

(Optional Format 1-2-96)